

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON)
TALCUM POWDER PRODUCTS)
MARKETING, SALES PRACTICES AND) MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION)

This Document Relates To All Cases)

)

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT,
LLC'S MEMORANDUM OF LAW IN OPPOSITION TO THE
PLAINTIFFS' STEERING COMMITTEE'S MOTION TO EXCLUDE THE
OPINIONS OF DRS. MICHAEL FINAN, CHERYL SAENZ AND KEVIN
HOLCOMB**

**FAEGRE DRINKER BIDDLE &
REATH LLP**
*A Delaware Limited Liability
Partnership*
600 Campus Drive
Florham Park, New Jersey 07932
(973) 549-7000

**SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP**
One Manhattan West
New York, NY 10001-8602
(212) 735-3000

*Attorneys for Defendants Johnson &
Johnson and LLT Management, LLC*

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	3
A. Drs. Saenz, Holcomb And Finan.....	3
B. Drs. Saenz, Holcomb And Finan’s Relevant Opinions.....	7
1. General Causation Opinions	7
2. Specific Causation Opinions	10
ARGUMENT.....	15
II. DRS. SAENZ, HOLCOMB AND FINAN’S OPINIONS REGARDING POTENTIAL GENETIC CAUSES OF THE PLAINTIFFS’ CANCERS ARE BASED ON RELIABLE SCIENTIFIC EVIDENCE	16
III. DRS. SAENZ, HOLCOMB AND FINAN’S BIOLOGICAL PLAUSIBILITY OPINIONS SATISFY RULE 702.	25
A. The Three Experts Properly Consider Talcum Powder As A Whole.	25
B. Drs. Saenz, Holcomb And Finan Properly Reject Plaintiffs’ Experts’ Biological Plausibility Opinions As Unsupported By Reliable Scientific Evidence.	33
CONCLUSION	39

TABLE OF AUTHORITIES

	<u>Page(s)</u>
CASES	
<i>In re Abilify (Aripiprazole) Products Liability Litigation</i> , 299 F. Supp. 3d 1291 (N.D. Fla. 2018)	15
<i>In re Accutane Products Liability</i> , 511 F. Supp. 2d 1288 (M.D. Fla. 2007)	34
<i>Burst v. Shell Oil Co.</i> , No. CIV.A. 14-109, 2015 WL 3755953 (E.D. La. June 16, 2015)	32
<i>In re Fosamax Products Liability Litigation</i> , 645 F. Supp. 2d 164 (S.D.N.Y. 2009)	34, 35
<i>In re Hanford Nuclear Reservation Litigation</i> , No. 91-3015, 1998 WL 775340 (E.D. Wash. Aug. 21, 1998)	35
<i>Henricksen v. ConocoPhillips Co.</i> , 605 F. Supp. 2d 1142 (E.D. Wash. 2009)	32
<i>In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices & Products Litigation</i> , 509 F. Supp. 3d 116 (D.N.J. 2020)	passim
<i>Milward v. Acuity Specialty Products Group, Inc.</i> , 639 F.3d 11 (1st Cir. 2011)	35
<i>In re Mirena IUD Products Liability Litigation</i> , 169 F. Supp. 3d 396 (S.D.N.Y. 2016)	35
<i>In re Mirena IUS Levonorgestrel-Related Products Liability Litigation</i> , 341 F. Supp. 3d 213 (S.D.N.Y. 2018)	34
<i>National Union Fire Insurance Co. of Pittsburgh PA v. SPX Flow US, LLC</i> , No. 18-80332, 2019 WL 1227987 (S.D. Fla. Mar. 14, 2019)	16, 17

<i>In re Pfizer Inc. Securities Litigation,</i> No. 04-9866, 2010 WL 1047618 (S.D.N.Y. Mar. 22, 2010).....	35
<i>Shadrick v. Southern Health Partners, Inc.,</i> No. 11-00033, 2016 WL 4555611 (W.D. Ky. Aug. 31, 2016).....	2, 16, 17
<i>Soldo v. Sandoz Pharmaceuticals Corp.,</i> 244 F. Supp. 2d 434 (W.D. Pa. 2003)	34
<i>In re Trasylol Products Liability Litigation,</i> No. 08-01928, 2010 WL 1489730 (S.D. Fla. Mar. 19, 2010)	35
<i>In re Zantac (Ranitidine) Products Liability Litigation,</i> 644 F. Supp. 3d 1075 (S.D. Fla. Dec. 6. 2022).....	31
<i>In re Zyprexa Products Liability Litigation,</i> 489 F. Supp. 2d 230 (E.D.N.Y. 2007)	2

OTHER AUTHORITIES

<i>Egli & Newton, The Transport of Carbon Particles in the Human Female Reproductive Tract,</i> 12(2) Fertil. Steril. 151, 152 (1961)	39
<i>Thomas D. Schroeder, Toward a More Transparent Approach to Considering the Admission of Expert Testimony,</i> 95 Notre Dame L. Rev. 2039, 2043-44 (2020)	35
<i>Sia, Treatment of Ovarian Clear Cell Carcinoma with Immune Checkpoint Blockade: A Case Series,</i> 32(8) Int'l J. Gynecol. Cancer 1017 (2022).....	23
<i>Terry, Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls,</i> 6(8) Cancer Prev. Res. 811 (2013).....	12

INTRODUCTION

Plaintiffs seek to partially exclude the opinions of Drs. Michael Finan, Cheryl Saenz and Kevin Holcomb, three highly regarded and exceedingly well-credentialed physicians who specialize in the practice of gynecological oncology. Specifically, plaintiffs seek to prevent these experts from testifying that: (1) certain genetic mutations that are presently unknown, or the significance of which has not been determined, may have caused the bellwether plaintiffs' ovarian cancers; and (2) plaintiffs' experts have not shown that their theory of causation is biologically plausible.

Notably, plaintiffs ***do not*** seek to bar these witnesses from offering the vast majority of their opinions, which address:

- the epidemiological literature on talc and ovarian cancer;¹
- whether all of the Bradford Hill criteria relevant to evaluating the purported association between talc and ovarian cancer—aside from biological plausibility—are satisfied;²
- the established risk and protective factors for the development of ovarian cancer;³ and

¹ (See Rep. of Michael Finan (“Finan Rep.”) at 17-44, May 28, 2024 (Pls.’ Br. Ex. 3); Rep. of Kevin Holcomb (“Holcomb Rep.”) at 7-18, May 28, 2024 (Pls.’ Br. Ex. 2); Am. Rep. of Cheryl Saenz (“Saenz 2024 MDL Rep.”) at 19-42, May 21, 2024 (Pls.’ Br. Ex. 1).)

² (See Finan Rep. at 44-62; Holcomb Rep. at 23-28; Saenz 2024 MDL Rep. at 18-42.)

³ (See Finan Rep. at 6-11; Holcomb Rep. at 4-7; Saenz 2024 MDL Rep. at 3-16.)

- the experts’ critiques of the specific causation methodologies applied by plaintiffs’ experts.

Even though plaintiffs’ challenges are narrow, they are utterly without merit.

First, plaintiffs argue that defendants’ experts should not be allowed to testify about potential unknown genetic causes of ovarian cancer—including genetic variants of unknown significance (“VUS”)—because the experts cannot prove that such genetic factors are probable causes of any of the bellwether plaintiffs’ cancers. This argument is based on a fundamental misunderstanding of the disparate roles of plaintiff and defense experts. Although Rule 702 applies to all expert testimony, “defendants’ experts have a less demanding task, since they have no burden to produce models or methods of their own,” *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007), and can thus testify to mere possibilities rather than probabilities, *Shadrick v. S. Health Partners, Inc.*, No. 11-00033, 2016 WL 4555611, at *10 (W.D. Ky. Aug. 31, 2016).

Second, plaintiffs criticize defendants’ experts’ biological plausibility opinions on the ground that they fail to consider the individual components of talc. This argument violates the Court’s April 30, 2024 Order because it regurgitates an argument that was already rejected by Judge Wolfson without explaining why her opinion was either erroneous or has been superseded by scientific or legal developments. The argument is also frivolous because the three experts at issue are responding to opinions offered by plaintiffs’ experts, who themselves focus on

the product as it was sold, rather than its separate constituents. Moreover, courts in similar cases have rejected plaintiffs' experts' attempts to analyze the individual components of a substance, rather than the whole, in determining whether the substance caused a particular injury.

Finally, plaintiffs argue that the three gynecologic oncologists improperly seek to hold plaintiffs' experts to a standard of "certainty" with respect to the biological plausibility factor of the Bradford Hill framework. Not so. The gist of the opinions offered by Drs. Saenz, Holcomb and Finan is not that plaintiffs' experts must have absolute proof of biological plausibility, but rather that biological plausibility means something more than an untested hypothesis, or one that is unsupported by any reliable science.

BACKGROUND

A. Drs. Saenz, Holcomb And Finan

Dr. Saenz is a Clinical Professor of Gynecologic Oncology in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Diego.⁴ Her responsibilities in her current position as an educator include teaching fellows, residents and medical students about all aspects of gynecologic malignancies, including epidemiology, risk factors for development, histopathology and pathophysiology, prevention, diagnosis and

⁴ (Saenz 2024 MDL Rep. at 1.)

treatment of gynecologic cancers.⁵ Dr. Saenz has more than 20 years of experience as an attending physician at UC San Diego Health System, where she performs surgical procedures and prescribes chemotherapy and immunotherapy for patients with reproductive cancers.⁶ Dr. Saenz is an active researcher in the area of gynecologic oncology, and has published research in numerous journals regarding ovarian, cervical and endometrial cancers.⁷ One of her active areas of research is the early detection of ovarian cancer.⁸ She is also a member of several organizations in the areas of gynecology and/or oncology, including the Society of Gynecologic Oncology, and served on the Board of Directors of the Foundation for Women's Cancer from 2007-2013, including as the Chair of the Foundation's Education Committee from 2013-2016.⁹

Dr. Holcomb is an Associate Professor of Clinical Obstetrics and Gynecology at Weill Cornell Medical College.¹⁰ He also serves as the Director of Gynecologic Oncology, Vice-Chairman of Gynecology, and Director of Minimally

⁵ (Id.)

⁶ (Id.)

⁷ (Id. at 1-2.)

⁸ (Id. at 2.)

⁹ (Id. at 2-3.)

¹⁰ (Holcomb Rep. at 1.)

Invasive Surgery in Weill Cornell’s Department of Obstetrics and Gynecology.¹¹

Dr. Holcomb holds an M.D. from New York Medical College and a B.A. from Cornell University.¹² The majority of Dr. Holcomb’s time is spent in clinical practice as a gynecologic oncologist; he has performed approximately 200 surgeries per year since the early 2000s and treats approximately 20 new ovarian cancer patients per year.¹³ Dr. Holcomb’s clinical responsibilities also include assessing cancer risk in his patients through the identification of genetic, reproductive and environmental risk factors.¹⁴

As part of his duties, Dr. Holcomb reviews pathology slides for every patient on whom he operates for ovarian cancer.¹⁵ In addition, as part of his role on the tumor board for Weill Cornell, he reviews slides of precursor lesions for high grade serous ovarian cancer from women (typically with genetic mutations) who undergo risk-reducing surgery.¹⁶

Dr. Holcomb has authored or co-authored more than 100 peer-reviewed articles and is currently the principal investigator for two multi-institutional

¹¹ (*Id.*)

¹² (Holcomb CV at 1 (Ex. 1 to Decl. of Jessica Davidson (“Davidson Decl.”)).)

¹³ (Holcomb Rep. at 1.)

¹⁴ (*Id.* at 1-2.)

¹⁵ (Dep. of Kevin Holcomb (“3/27/19 Holcomb Dep.”) 450:9-16 (Pls.’ Br. Ex. 21).)

¹⁶ (*Id.* 449:1-452:4.)

prospective trials examining the role of a biomarker in the early detection of ovarian cancer.¹⁷ Dr. Holcomb acts as a reviewer of research submitted for publication to several journals, including Gynecologic Oncology, and makes recommendations regarding the appropriateness and validity of the submitted research based on assessment of the study design, statistical analysis and presentation of the findings.¹⁸

Dr. Finan has over 30 years of experience treating women with ovarian cancer.¹⁹ He is a clinical gynecologist who serves as Chief of Oncology Services and Women's Services for the Singing River Health System in Mississippi.²⁰ In that role, Dr. Finan oversees clinical research and a Cancer Risk Assessment Program that assesses cancer risk for certain female patients based on family history and offers genetic testing and other screening when appropriate. On average, Dr. Finan sees 25-30 women per week in his clinic and conducts 6-8 surgical procedures per week.²¹ Previously, Dr. Finan provided clinical care, taught, and conducted research as the Cancer Center Director at the University of

¹⁷ (Holcomb Rep. at 2; Holcomb CV at 8-16.)

¹⁸ (Holcomb Rep. at 2.)

¹⁹ (Finan Rep. at 2.)

²⁰ (*Id.*)

²¹ (*Id.* at 3-4.)

South Alabama Mitchell Cancer Institute.²² One of Dr. Finan's research projects involved developing an innovative screening test for early detection of ovarian cancer, for which Dr. Finan holds several patents.²³

Dr. Finan has lectured and published extensively on subjects related to ovarian cancer, has held numerous leadership positions at organizations in the areas of gynecology and/or oncology, and has devoted substantial time to reviewing papers and studies for publications on these subjects.²⁴

B. Drs. Saenz, Holcomb And Finan's Relevant Opinions

Drs. Saenz, Holcomb and Finan all respond to plaintiffs' experts' opinions that talc use causes ovarian cancer generally, as well as plaintiffs' experts' specific causation opinions with respect to the individual bellwether plaintiffs.

1. General Causation Opinions

Drs. Saenz, Holcomb and Finan all opine that the scientific evidence does not support the conclusion that talc can cause ovarian cancer because, among other reasons, the purported associations reported in the epidemiological literature are either weak or non-existent, as well as highly inconsistent, and there is also no evidence of a dose-response with respect to talc use and instances of ovarian

²² (*Id.*)

²³ (*Id.* at 3.)

²⁴ (Finan Rep. at 2-4; Finan CV (Ex. 2 to Davidson Decl.))

cancer. Moreover, Drs. Saenz, Holcomb and Finan all opine that plaintiffs' theories regarding the biological mechanism by which talc exposure allegedly causes ovarian cancer are premised on rank speculation that is unsupported by science.

Specifically, all three experts testify, based on their examination of the scientific literature, that there is no basis to support plaintiffs' theory that talc applied to the perineum can migrate through the genital tract and reach the fallopian tubes or ovaries.²⁵ Dr. Saenz examines various studies that have purported to find talc in ovaries and explains why they do not support plaintiffs' theories—and also notes that no “single human study has ever been published that has actually documented the migration of particulate matter from the perineum through the entire female reproductive tract to the ovary.”²⁶ Dr. Holcomb similarly opines that neither human nor animal studies support plaintiffs' mechanistic theories and explains that these theories are incompatible with the fact there is inconsistent data as to whether tubal ligation or hysterectomy has a protective effect with respect to ovarian cancer.²⁷ And Dr. Finan notes that the literature plaintiffs' experts cite as supporting an upward migration of talc through the

²⁵ (Finan Rep. at 49-54; Saenz 2024 MDL Rep. at 42-44; Holcomb Rep. at 26.)

²⁶ (See Saenz 2024 MDL Rep. at 42-44.)

²⁷ (See Holcomb Rep. at 19-21.)

female reproductive system is irrelevant because the studies used “many artificial measures that do not translate into a woman applying talcum powder to her perineum.”²⁸

In addition, all three experts opine that there is insufficient scientific support for plaintiffs’ speculative theory that talc causes ovarian cancer by inducing chronic inflammation.²⁹ Dr. Saenz opines that such a theory is inconsistent with: (1) what she has seen in her decades of experience; (2) the fact that pelvic inflammatory disease is not associated with the development of high grade serous ovarian cancer; and (3) the fact that anti-inflammatory drugs, such as NSAIDS, are inconsistently associated with a decreased risk of ovarian cancer.³⁰ Dr. Finan similarly opines that the scientific literature merely suggests that inflammation is associated with ***advanced*** ovarian cancer, not ovarian cancer development.³¹

Similarly, all three experts opine that there is no reliable data that talc can induce malignant transformation in ovarian cells—critiquing the studies that plaintiffs’ experts rely on in opining otherwise.³² Moreover, Dr. Saenz explains

²⁸ (See Finan Rep. at 50.)

²⁹ (See *id.* at 54-60; Saenz 2024 MDL Rep. at 44-49; Holcomb Rep. at 21-23.)

³⁰ (See Saenz 2024 MDL Rep. at 44-46.)

³¹ (See Finan Rep. at 54.)

³² (Finan Rep. at 60-63; Saenz 2024 MDL Rep. at 49-54; Holcomb Rep. at 26-27.)

that plaintiffs' theory that talc is a vehicle by which other substances, namely asbestos, cause ovarian cancer, is speculative and unsupported by the relevant epidemiological literature.³³

Drs. Saenz, Holcomb and Finan also offer opinions regarding the established risk factors for ovarian cancer, which includes genetic factors and variations. Of note, Dr. Finan explains that, while scientists have identified over two dozen genetic mutations that are related to ovarian cancer—including BRCA variations—additional genetic mutations continue to be identified and VUS are “commonly found to be associated with diseases as further testing is refined over time.”³⁴ Dr. Saenz notes that “there are still genes yet to be identified that will fall into the ‘BRCA-ness’ category” and that “perhaps as many as 30% of all ovarian cancers are actually linked to inheritance of” a “genetic malfunction.”³⁵

2. Specific Causation Opinions

Drs. Saenz, Holcomb and Finan also rebut opinions offered by plaintiffs' experts that talc was a substantial contributing factor in the bellwether plaintiffs' development of ovarian cancer. Drs. Saenz, Holcomb and Finan explain that neither Dr. Wolf—who offers specific causation opinions regarding plaintiffs

³³ (Saenz 2024 MDL Rep. at 54-58.)

³⁴ (See Finan Rep. at 7.)

³⁵ (See Saenz 2024 MDL Rep. at 7.)

Bondurant, Gallardo and Judkins—nor Dr. Clarke-Pearson—who offers such opinions with respect to plaintiffs Converse, Newsome and Rausa—based their opinions on a valid methodology. While both experts claim to have applied a “differential diagnosis”—which requires an expert to “rule in” an exposure as a cause of a plaintiff’s injury and “rule out” all other potential causes—neither performed that methodology reliably. For example, Dr. Wolf simply assumed that both Ms. Gallardo and Ms. Judkins’ ovarian cancers were caused by talc because these plaintiffs allegedly have few or no established risk factors for cancer.³⁶ As Drs. Saenz and Holcomb explain, such an approach “is not consistent with sound medical or scientific practice.”³⁷

Drs. Saenz, Holcomb and Finan also explain that neither of plaintiffs’ specific causation experts properly “ruled in” talc as a cause of any of the plaintiffs’ cancers because there is “no credible scientific data” that talc increases the risk of their specific cancer subtypes.³⁸ This is particularly true with respect to

³⁶ (See Holcomb Rep. at 33; Rep. of Cheryl Saenz Re: Carter Judkins (“Saenz Judkins Rep.”) at 5-6, May 28, 2024 (Pls.’ Br. Ex. 5).)

³⁷ (Holcomb Rep. at 33; *see also* Saenz Judkins Rep. at 5-6 (noting Dr. Wolf’s approach runs afoul of “[s]ound medical judgment”).)

³⁸ (See Rep. of Cheryl Saenz Re: Tamara Newsome (“Saenz Newsome Rep.”) at 7, May 28, 2024 (Pls.’ Br. Ex. 6); *see also* Rep. of Cheryl Saenz Re: Pasqualina Rausa (“Saenz Rausa Rep.”) at 6, May 28, 2024 (Pls.’ Br. Ex. 7) (noting “there is no reliable way to rule in talc as a cause of ovarian cancer and [Dr. Clarke-Pearson] did not reliably rule out other risk factors”).)

plaintiffs Bondurant and Converse, who were diagnosed with clear cell carcinoma. As Drs. Saenz and Finan explain, plaintiffs' experts improperly relied on one study³⁹ that found a statistically significant association between talc and clear cell carcinoma, ignoring inconsistencies in that study's underlying data,⁴⁰ while overlooking the many other studies that have found **no** statistically significant association between talc use and clear cell carcinoma.

Additionally, Saenz, Holcomb and Finan explain that plaintiffs' experts' specific causation opinions are flawed because these experts fail to adequately "rule out" potential alternative causes of the various plaintiffs' cancers, including potential genetic causes. For example:

Linda Bondurant. Dr. Finan opines that Ms. Bondurant's clear cell ovarian cancer may be the result of the several risk factors for this subtype, including her endometriosis, her strong family history of cancer—including cancers of the pancreas, ovaries and breasts—her age, and her genetics.⁴¹ With respect to genetics, Dr. Finan notes that genetic testing on Ms. Bondurant revealed that she had a pathogenic variant in the SDHA gene which is associated with a 10% risk of

³⁹ Terry, *Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls*, 6(8) *Cancer Prev. Res.* 811 (2013) (Ex. 3 to Davidson Decl.).

⁴⁰ (Finan Rep. at 66-67; Rep. of Cheryl Saenz Re: Hilary Converse ("Saenz Converse Rep.") at 9-11, May 28, 2024 (Pls.' Br. Ex. 4).)

⁴¹ (Finan Rep. at 63-67.)

developing tumors by the age of 70, as well as a variant of unknown significance in the PTCH1 gene.

Anna Gallardo. Dr. Holcomb opines that Ms. Gallardo had a number of risk factors that could have played a role in her development of endometrioid ovarian cancer. Specifically, Dr. Holcomb explains that Ms. Gallardo’s extensive family history of cancer and her use of hormone replacement therapy during menopause put her at increased risk of endometrioid cancer.⁴² Moreover, he opines that he could not rule out genetics as a possible source of Ms. Gallardo’s ovarian cancer because she was not “tested for” several potentially relevant “genetic mutations” that “are standard components of current ovarian cancer predisposition testing.”⁴³

Hilary Converse. Dr. Saenz opines that Ms. Converse has several well-established risk factors that could have contributed to her clear cell carcinoma. This includes her age at diagnosis, Ashkenazi heritage, endometriosis, use of hormone replacement therapy, as well as her genetics.⁴⁴ Dr. Saenz explains that Ms. Converse’s genetic testing revealed she had two variants of unknown significance in the ATM and TGFBR2 genes that could potentially have been the

⁴² (Holcomb Rep. at 31-33.)

⁴³ (*Id.* at 33.)

⁴⁴ (Saenz Converse Rep. at 12.)

cause of her disease.⁴⁵

Anne Carter Judkins. Dr. Saenz also opines that genetics cannot be ruled out as a possible cause of Ms. Judkins' high grade serous carcinoma of the right ovary. She notes that Ms. Judkins tested positive for a variant of unknown significance in the PTEN gene on the Ambry panel.⁴⁶ Moreover, Dr. Saenz opines that there is no scientific basis for attributing Ms. Judkins's ovarian cancer to talc, especially given that Dr. Godleski did not find any talc in her right ovary and, in the locations where Dr. Godleski did find particles he suspected were talc, there was no evidence of inflammatory response.⁴⁷

Tamara Newsome. Dr. Saenz opines that Ms. Newsome had two primary risk factors for her endometrioid cancer: her age and endometriosis.⁴⁸ Moreover, she opines that there is also a possibility that Ms. Newsome carries a germline mutation that science has not yet identified as a risk factor for the development of ovarian cancer—and also notes that genetic tests found that Ms. Newsome has a variant of unknown significance in the MUTYH gene on the Myriad panel.⁴⁹

Pasqualina Rausa. Dr. Saenz notes that there is a possibility that Ms. Rausa

⁴⁵ (*Id.* at 3.)

⁴⁶ (*Saenz Judkins* Rep. at 3-5.)

⁴⁷ (*Id.* at 4.)

⁴⁸ (*Saenz Newsome* Rep. at 4.)

⁴⁹ (*Id.*)

is carrying a germline mutation that has not yet been identified as a risk factor for ovarian cancer.⁵⁰ In addition, she opines that Ms. Rausa’s cancer most likely developed sporadically and therefore has no distinct cause.⁵¹ Dr. Saenz also explains that plaintiffs’ expert Dr. Clarke-Pearson’s assertion that Ms. Rausa’s cancer was caused by talc exposure is inconsistent with the fact that no talc particles were found at the locations of Ms. Rausa’s cancer—and there is no evidence of a foreign body response in the locations where Dr. Godleski reported finding talc-like particles in Ms. Rausa’s tissue samples.⁵²

ARGUMENT

The standard governing the admissibility of defense expert testimony is set forth in Defendants’ Opposition to Plaintiffs’ Motion to Partially Exclude the Opinions of Drs. Permuth, DiFeo and Boyd (incorporated herein).⁵³ As set forth in that brief, it is “entirely appropriate” for defendants’ experts to offer what are, “essentially, critiques of [p]laintiffs’ experts’ evidence, methodologies, and conclusions.” *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018). In addition, “a defendant may offer evidence of potential

⁵⁰ (Saenz *Rausa* Rep. at 5.)

⁵¹ (*Id.*)

⁵² (*Id.* at 6.)

⁵³ (See Defs.’ Mem. of Law in Opp’n to Pls.’ Mots. to Exclude Ops. of Drs. Jennifer Permuth, Analisa DiFeo, and Jeff Boyd, filed herewith.)

alternative causes of a disease or injury without needing to prove those alternative-cause theories with certainty or probability.” *Nat'l Union Fire Ins. Co. of Pittsburgh PA v. SPX Flow US, LLC*, No. 18-80332, 2019 WL 1227987, at *4 (S.D. Fla. Mar. 14, 2019); *Shadrick*, 2016 WL 4555611, at *10 (“[d]efense experts are not bound by the ‘probability’ standard and may introduce testimony couched only in terms of ‘possibility’”) (citation omitted). The opinions of Drs. Saenz, Holcomb and Finan that plaintiffs seek to exclude are admissible under this standard. As a result, plaintiffs’ motion should be denied.

II. DRS. SAENZ, HOLCOMB AND FINAN’S OPINIONS REGARDING POTENTIAL GENETIC CAUSES OF THE PLAINTIFFS’ CANCERS ARE BASED ON RELIABLE SCIENTIFIC EVIDENCE.

Plaintiffs assert that it is too “speculative” and “misleading” for Drs. Saenz, Holcomb and Finan to explain to the jury that there are undiscovered genetic causes of ovarian cancer—and also variations of presently-unidentified significance to the development of ovarian cancer—and therefore plaintiffs’ experts cannot reliably rule out genetics as a cause of each plaintiff’s ovarian cancer.⁵⁴ Plaintiffs’ argument should be rejected.

First, there is no merit to plaintiffs’ assertion that Drs. Saenz, Holcomb and Finan’s opinions that unknown genetic variations—and known variants of unknown significance or VUS—may have caused plaintiffs’ cancers are

⁵⁴ (Pls.’ Br. at 5-10.)

impermissibly “speculative”⁵⁵ because these experts cannot conclusively prove that each plaintiff has such variations and that they caused her cancer. As set forth above, defense experts such as Drs. Saenz, Holcomb and Finan are permitted to identify “evidence of potential alternative causes of a disease or injury” that undermines plaintiffs’ theory of causation, and they do not “need[] to prove those alternative-cause theories with certainty or probability.” *Nat'l Union Fire Ins. Co.*, 2019 WL 1227987, at *4. Because plaintiffs bear the burden of proof on causation, defense experts need only “produce ‘credible evidence which tends to discredit or rebut the plaintiff’s evidence.’” *Shadrick*, 2016 WL 4555611, at *10 (citations omitted).

That is precisely what Drs. Saenz, Holcomb and Finan intend to do in this case. As set forth below, each of these experts offers critiques of plaintiffs’ experts’ specific causation opinions, including those experts’ failure to consider genetic variants of unknown significance—as well as genetic variations that have yet to be identified—that may be responsible for the plaintiffs’ various cancer subtypes.

Dr. Saenz. In her report, Dr. Saenz responds to plaintiffs’ experts’ causation opinions with respect to plaintiffs Rausa, Newsome, Converse and Judkins. As Dr. Saenz explains, genetic mutations are one of the most well-

⁵⁵ (*Id.* at 5-6.)

established risk factors for ovarian cancer, with the majority of relevant mutations found in either the BRCA 1 or BRCA 2 genes, which were only discovered in the mid-1990s.⁵⁶ Dr. Saenz notes, however, that the science is still developing, with new genes potentially connected to ovarian cancer being discovered to this day. Thus, “[i]t is presently thought that there are still genes to be identified that will fall into the ‘BRCA-ness’ category that will ultimately reveal that perhaps as many as 30% of all ovarian cancers are actually linked” to genetic factors.⁵⁷ Dr. Saenz opines that the cancers experienced by each of the four plaintiffs at issue could have been the result of genetic variations that have yet to be conclusively identified.

For example, Dr. Saenz explains that plaintiff Converse, who was diagnosed with clear cell carcinoma, may have a germline mutation that contributed to her ovarian cancer that has yet to be identified.⁵⁸ In support of this opinion, she notes that, after genetic testing in 2008 found no genetic mutation in BRCA1 or 2, Ms. Converse’s own genetic counselors stated that it was possible there is an undetectable mutation in a different gene causing the strong history of cancers in her family. In 2014, testing revealed two variants of unknown significance in the

⁵⁶ (See Saenz 2024 MDL Rep. at 5-6.)

⁵⁷ (See *id.* at 7.)

⁵⁸ (Saenz *Converse* Rep. at 5.)

ATM and TGFBR2 genes—the same genetic variants shared by her mother, who was diagnosed with breast cancer at age 46.⁵⁹ While the impact of these VUSs is unknown, Ms. Converse’s genetic counselors at Yale counseled her that she was at an increased risk of breast cancer despite otherwise testing negative.⁶⁰ Dr. Saenz points out that the counselors even considered Ms. Converse’s daughter to be at increased risk for ovarian and breast cancer for genetic reasons.⁶¹ Thus, the counselors further recommended that both Ms. Converse and her daughter remain in intensive screening and that they check back in periodically for new testing.⁶²

Similarly, Dr. Saenz notes that while plaintiff Rausa, who was diagnosed with high-grade serous ovarian cancer, had negative germline testing for 45 genes, it is possible she is carrying an unidentified germline mutation that contributed to her ovarian cancer.⁶³ Dr. Saenz further opines that, had Ms. Rausa consulted a genetics counselor regarding these results, she would have been informed that “this negative result does not necessary mean that her cancer was sporadic (i.e., not attributable to an inherited predisposition).”⁶⁴ According to Dr. Saenz, this is so

⁵⁹ (Id. at 2-3.)

⁶⁰ (Id. at 3.)

⁶¹ (Id. at 3, 5.)

⁶² (Id.)

⁶³ (Saenz Rausa Rep. at 5.)

⁶⁴ (Id. at 4.)

because: (1) the genetic testing Ms. Rausa underwent was not comprehensive and research continues to find new genes and mutations; and (2) certain mutations in genes “may be missed by current technology.”⁶⁵ Moreover, Dr. Saenz notes that a VUS was detected in Ms. Rausa’s FH gene, which is thought to be deleterious to health.⁶⁶

As for plaintiff Judkins, who was diagnosed with high grade serous carcinoma in the right ovary, Dr. Saenz similarly explains that even though she had negative germline testing for 24 out of 25 genes, it is possible she is carrying an unidentified germline mutation that contributed to her ovarian cancer.⁶⁷ Dr. Saenz’s opinions are in line with that of Ms. Judkins’ own genetic counselor, who informed Ms. Judkins that a negative result does not necessarily mean her cancer was not due to an inherited predisposition because: (1) her test concerning 25 genes was not comprehensive; and (2) a small percentage of mutations in the genes she was tested for may be missed by current technology.⁶⁸ Moreover, Ms. Judkins’ genetic testing did reveal a VUS in the PTEN gene.⁶⁹

Finally, Dr. Saenz explains that a VUS was detected in Ms. Newsome’s

⁶⁵ (*Id.*)

⁶⁶ (*Saenz Rausa* Rep. at 4.)

⁶⁷ (*Saenz Judkins* Rep. at 4-5.)

⁶⁸ (*Id.* at 3 & n.5 (citing *JudkinsC-DHMCMR-00575*).)

⁶⁹ (*Id.* at 3.)

MUTYH gene.⁷⁰ She also opines that even though Ms. Newsome was negative for a germline mutation in 25 of 26 genes tested, she may be carrying a germline mutation that science has yet to identify that contributed to her ovarian cancer.⁷¹ In addition, Dr. Saenz notes the limits of the genetic testing performed on Ms. Newsome; specifically, she was only tested for mutations on certain genes,⁷² and the methods used at the time may have missed mutations even on the genes that were tested.⁷³

Dr. Holcomb. Dr. Holcomb responds to plaintiffs' experts' specific causation opinions with respect to Ms. Gallardo. In his report, Dr. Holcomb explains that “[t]he number of genes potentially associated with an increased risk of ovarian cancer is continually expanding.”⁷⁴ Dr. Holcomb opines that a hereditary cause cannot be ruled out for Ms. Gallardo’s cancer because her genetic testing was performed in 2014, and she was not “tested for” several potentially relevant “genetic mutations” that “are standard components of current ovarian cancer predisposition testing.”⁷⁵ Notably, Ms. Gallardo’s own genetic testing

⁷⁰ (Saenz *Newsome* Rep. at 3.)

⁷¹ (*Id.* at 3.)

⁷² (*Id.*)

⁷³ (*Id.*)

⁷⁴ (Holcomb Rep. at 6.)

⁷⁵ (*Id.* at 33.)

report expressly states—consistent with Dr. Holcomb’s opinion—that a hereditary cause of Ms. Gallardo cancer could not be ruled out based on the testing, which addressed only 11 genes.⁷⁶

Dr. Finan. Dr. Finan responds to plaintiffs’ experts’ causation opinions regarding plaintiff Bondurant, who was diagnosed with clear cell ovarian carcinoma.⁷⁷ Dr. Finan explains that, while scientists have identified more than two dozen genetic mutations that are related to ovarian cancer, additional genetic mutations continue to be identified and VUSs are “commonly found to be associated with diseases as further testing is refined over time.”⁷⁸ He also notes that “over [his] years” as a gynecologic oncologist, he has had patients who “years ago . . . had a VUS” that was later “identified as pathogenic,” making it impossible to ignore the fact that mutations identified as having “unknown significance” today may be determined to be a cause of cancer in the future.⁷⁹

Dr. Finan notes that genetic testing for Ms. Bondurant found that she had a pathogenic variant in the SDHA gene that is associated with a 10% risk of

⁷⁶ (Id.)

⁷⁷ (Finan Rep. at 63.)

⁷⁸ (See *id.* at 7.)

⁷⁹ (Dep. of Michael Finan (“Finan Carl Dep.”) 111:18-112:4, *Carl v. Johnson & Johnson*, No. ATL-L-6546-14 (N.J. Super. Ct. Law Div. May 10, 2024) (Pls.’ Br. Ex. 11).)

developing tumors by the age of 70, as well as a VUS in the PTCH1 gene.⁸⁰ Dr. Finan points out that in a study addressing 16 patients with ovarian clear cell carcinoma, one patient had a SDHA genetic mutation similar to Ms. Bondurant's.⁸¹ Moreover, as Dr. Finan explained in his deposition, he is not “just looking at” the genes themselves “in isolation”; he also considers “them in combination with” each plaintiff’s “family history.”⁸² Notably, Ms. Bondurant has an extensive family history of cancer generally as well as breast and ovarian cancer,⁸³ making it possible that as-yet-unidentified genetic factors are at play. And because “new genetic variants [are] found to be associated with ovarian cancer on a regular basis,” Ms. Bondurant’s VUS cannot be ignored when assessing causation.⁸⁴

In short, the experts at issue have reasoned, there are scientific bases to raise the possibility of alternative, genetic causes of the plaintiffs’ cancers.

Second, there is also no merit to plaintiffs’ argument that any testimony offered by Drs. Saenz, Holcomb and Finan about unknown or unidentified genetic

⁸⁰ (Finan Rep. at 64.)

⁸¹ (*Id.* at 64 & n.200 (citing Sia, *Treatment of Ovarian Clear Cell Carcinoma with Immune Checkpoint Blockade: A Case Series*, 32(8) Int’l J. Gynecol. Cancer 1017 (2022))).

⁸² (Dep. of Michael Finan (“6/26/24 Finan Dep.”) 76:14-77:19, June 26, 2024 (Pls.’ Br. Ex. 8); *see also id.* 83:6-20 (noting that “it’s not just the gene mutation in isolation,” it is “that plus their family history”)).

⁸³ (Finan Rep. at 63-64.)

⁸⁴ (*Id.* at 64.)

variations would “mislead the jury into believing association of Plaintiffs’ ovarian cancers to an inherited genetic mutation is inevitable.”⁸⁵ None of the opinions plaintiffs challenge comes anywhere close to suggesting that it is certain or inevitable that the plaintiffs’ cancers will one day be linked to presently unknown genetic mutations. Instead, as plaintiffs themselves note, Drs. Saenz, Holcomb and Finan merely recognize a possibility that currently unidentified mutations “could” be associated with plaintiffs’ ovarian cancers. (See, e.g., Pls.’ Br. at 5 (objecting to Dr. Saenz’s opinion that plaintiff Judkins “**may** carry a germline mutation” which could have contributed to her development of cancer) (emphasis added) (citation omitted); *id.* at 5-6 (objecting to Dr. Saenz’s opinion that “there is still a **possibility** that” plaintiffs Newsome, Rausa and Converse are carrying a germline mutation which could have “contributed to [their] development of cancer”) (emphasis added) (citation omitted); *id.* at 6 (objecting to Dr. Finan’s opinion that does not automatically discount the import of Ms. Bondurant’s genetic testing, which revealed a VUS in the PTCH1 gene, because “genetic testing is a dynamic field with new genetic variants found to be associated with ovarian cancer on a regular basis.”); *id.* (objecting to Dr. Holcomb’s testimony that based on Ms. Gallardo’s genetic testing, one could “not rule out a hereditary cause of her ovarian cancer—a fact noted by her genetic testing report”) (see Holcomb Rep. at 33).)

⁸⁵ (Pls.’ Br. at 9-10.)

Neither Dr. Saenz, Dr. Holcomb nor Dr. Finan seeks to tell the jury that it is inevitable that science will one day prove that each of the bellwether plaintiffs' cancers was caused by a genetic mutation. Instead, each of these experts appropriately criticizes plaintiffs' experts' specific causation opinions by explaining that, because the science of genetic testing is a rapidly evolving field, it is *possible* that: (1) the genetic variations currently designated as being of "unknown significance" may one day be proven to have a link to cancer; and (2) scientists may at some point identify new genetic mutations related to cancer for which these plaintiffs have not yet been tested. This is proper rebuttal expert testimony that will not confuse or mislead the jury.

III. DRS. SAENZ, HOLCOMB AND FINAN'S BIOLOGICAL PLAUSIBILITY OPINIONS SATISFY RULE 702.

A. The Three Experts Properly Consider Talcum Powder As A Whole.

Even though their own experts largely attack talcum powder as one product, plaintiffs criticize defendants' experts for failing to address whether "the individual ingredients in talcum powder, including . . . asbestos, fibrous talc, platy talc, heavy metals, or fragrances[,] can cause or increase the risk of ovarian cancer."⁸⁶ This argument fails for several reasons.

⁸⁶ (Pls.' Br. at 3.)

First, plaintiffs' argument violates the Court's April 30, 2024 Order, which states as follows:

if Chief Judge Wolfson entered a decision on an issue and either party wishes to challenge that decision, briefing on the upcoming in limine motions should set forth Chief Judge Wolfson's previous decision and on what basis the party contends that decision should be reconsidered. In other words, the briefing should identify either: (1) that Chief Judge Wolfson's previous Opinion demonstrably fails to adhere to Rule 702 as clarified by the 2023 amendments; or (2) new science is shown to directly contradict or challenge Chief Judge Wolfson's previous findings.

(ECF No. 32122 at 6.) In the first round of *Daubert* briefing, plaintiffs argued to Judge Wolfson that one of defendants' experts' opinions was "unreliable because [the expert (Dr. Ben Neel)] did not consider the components of talc," faulting him "for not analyzing whether talc contains known carcinogens, such as asbestos or other heavy metals." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 196-97 (D.N.J. 2020). Judge Wolfson rejected plaintiffs' argument, holding that there was no requirement for the defense expert to "opine as to the components of talc" because he "has been proffered as an expert to rebut the methodology" of plaintiffs' expert, who opines that "talc *itself*" can cause ovarian cancer. *Id.* at 197.⁸⁷ Plaintiffs do not even acknowledge that ruling, let alone explain why it should be reconsidered.

⁸⁷ At the beginning of her opinion, Chief Judge Wolfson explained that "the reasoning in this Court's Opinion, applies with equal force to the remainder of the pending *Daubert* motions." *In re Johnson & Johnson*, 509 F. Supp. 3d at 128-29.

Second, putting aside the procedural flaw in plaintiffs' argument, it should be rejected for all the same reasons Judge Wolfson rejected it the first time. Defendants' experts are responding to plaintiffs' experts and scientific studies that address cosmetic talc as it is sold with all its constituents. When asked about whether the potential presence of asbestos in talc mattered to his opinions, Dr. Finan testified: "What I said was talcum powder, regarding – regardless of its constituents, whatever's in it is not causing cancer."⁸⁸ Drs. Saenz and Holcomb similarly opined that there is no evidence that talc, regardless of its exact constituents, causes or contributes to the development of ovarian cancer.⁸⁹ As Dr.

⁸⁸ (See, e.g., Finan *Carl* Dep. 279:21-280:10; Finan Rep. at 4 ("The application of talcum powder, *regardless of its constituents*, to the female perineum does not cause or contribute to the development of ovarian cancer.") (emphasis added).)

⁸⁹ (Saenz 2024 MDL Rep. at 58 ("My opinion does not change regardless of the composition of talcum powder because the published, peer-reviewed literature does not support an increased risk of developing ovarian cancer with perineal application of talc"); Dep. of Cheryl Saenz ("3/13/19 Saenz Dep.") 65:20-68:17, Mar. 13, 2019 (Pls.' Br. Ex. 22) (testifying that "[m]y opinion is that baby powder products do not increase the risk of developing ovarian cancer, regardless of what the constituent products are in that product," such as asbestos); Dep. of Cheryl Saenz ("6/20/24 Saenz Dep.") 533:10-22, June 20, 2024 (Pls.' Br. Ex. 13) ("[M]y opinion is based upon the literature for the perineal application of talcum powder, and that literature does not support an increased risk of developing ovarian cancer. So what the constituents are of the talcum powder is not relevant to my report. Or opinion."); Dep. of Kevin Holcomb ("6/7/24 Holcomb Dep.") 40:8-23, June 7, 2024 (Pls.' Br. Ex. 10) ("You're asking me about what is in talcum powder . . . my opinion is whatever is in that bottle that has been subjected to decades of testing does not increase the risk of ovarian cancer. So I'm happy to go back and forth about what is in the bottle, what's on the website. It's -- it's not a -- it's not impacting my opinions."), 165:15-166:6 (same).)

Saenz explained when asked about whether she assumed talc is asbestos-free, “I don’t believe that [] the constituents of the baby powder actually matters to my opinion. My opinion is the same regardless, because I do believe that if there is a risk of developing ovarian cancer with the use of talc, regardless of what’s in that - in that product, there would be an increased risk of developing ovarian cancer, borne out in the literature.”⁹⁰

This is all the more true because as part of assessing the scientific evidence and methodologies and conclusions of plaintiffs’ experts, defendants’ experts examined the same studies that plaintiffs’ experts cited to support their opinions: studies that examine whether talcum powder can cause ovarian cancer, not studies about its individual components.⁹¹ Plaintiffs have never suggested that the studies on which their experts relied are irrelevant because they analyzed talcum powder as a whole.

⁹⁰ (3/13/19 Saenz Dep. 64:22-65:10; *see also id.* 67:2-68:10 (providing the same explanation when asked about fragrances); 180:8-15 (same); 361:2-362:17 (same); Dep. of Cheryl Saenz 497:7-498:3, June 19, 2024 (Pls.’ Br. Ex. 12) (same).)

⁹¹ (*See, e.g.*, Finan Rep. at 61-62 (identifying flaws in Dr. Wolf’s reliance on an in vitro study by Harper and Dr. Saed’s studies); Saenz 2024 MDL Rep. at 51-53 (noting Drs. Clarke-Pearson’s and Wolf’s reliance on Saed’s studies and identifying various problems with Saed’s studies); Holcomb Rep. at 20, 26-27 (identifying flaws in studies cited by Dr. Wolf and Dr. Saed’s studies).)

Plaintiffs' argument is particularly confusing because many of plaintiffs' experts express opinions about talc *as a whole* (and have sought to publish articles in the scientific literature to support plaintiffs' claims about talc as a whole). To be sure, some of plaintiffs' experts' reports mention in passing that various constituents of talc may be carcinogenic, toxic or inflammatory.⁹² But when asked whether they performed any scientific analysis to support their positions on these constituents, plaintiffs' experts repeatedly testified that they did not perform such analyses because they were analyzing the properties of talc as a whole. To quote plaintiffs' expert Dr. Clarke-Pearson:

I don't know what it is about talcum powder that caused her ovarian cancer. Could it be heavy metals? Could it be fragrances? Could it be

⁹² (See, e.g., 3d Am. Rep. of Jack Siemiatycki at 1 n.1, 27, 71, May 27, 2024 (Ex. 4 to Davidson Decl.) (expressing opinion based on assumption that commercially available talc contains asbestos, fibrous talc, heavy metals, and fragrances); 3d Am. Rep. of Anne McTiernan at 84, May 28, 2024 (Ex. 5 to Davidson Decl.) (“It is important to note that [commercially-available talc] is not asbestos-free. Talcum powder products contain other, potentially carcinogenic substances; of greatest concern is the presence of asbestos in talc, and the presence of talc with asbestiform fibers (fibrous talc), in these products.”); Rep. of Arch Carson at 4, Nov. 16, 2018 (Ex. 6 to Davidson Decl.) (“Talc deposits are often intermingled with asbestos and vice versa.”); 3d Am. Rep. of Daniel Clarke-Pearson (“Clarke-Pearson 3d Am. Rep.”) at 7-8, May 28, 2024 (Pls.’ Br. Ex. 16) (“Talcum powder also contains other carcinogens including asbestos, talc containing asbestiform fibers (fibrous talc), heavy metals such as nickel, chromium and cobalt (possible 2b), and other inflammatory agents, toxins, and carcinogens contained in the fragrance chemicals in talcum powder.”); Rep. of Judith Zelikoff at 7, Nov. 16, 2018 (Ex. 7 to Davidson Decl.) (“Defendants have claimed that asbestos has been ‘eliminated’ from cosmetic talc products. However, there is substantial evidence that talcum powder products still contain asbestos”)(footnote omitted).)

asbestos that we're not aware of? I would just say that Johnson's Baby Powder causes ovarian cancer. Whatever the constituents are, I don't think anybody can pin that down.⁹³

Dr. Cote similarly testified that she did not perform a scientific or comprehensive review of the components of talc because her opinion is about "talc as a whole. It was not the components. It was whatever was in the bottles or containers of talc that the women were using."⁹⁴ And Dr. Moorman echoed this sentiment, explaining "I -- I am not making, really, any assumptions that these [constituents] are in the products. My -- you know, my focus on the epidemiologic data is based on the use of the talc products, whatever is contained in them."⁹⁵ At least six other plaintiffs' experts offered similar testimony—i.e., that they analyzed the connection between ovarian cancer and talc as a whole, regardless of the constituents.⁹⁶

⁹³ (Dep. of Daniel Clarke-Pearson ("8/26/21 Clarke-Pearson Dep.") 292:23-294:12, Aug. 26, 2021 (Ex. 8 to Davidson Decl.).)

⁹⁴ (Dep. of Michele Cote 110:25-113:2, Mar. 21, 2024 (Ex. 9 to Davidson Decl.).)

⁹⁵ (Dep. of Patricia Moorman 295:25-298:10, Jan. 25, 2019 (Ex. 10 to Davidson Decl.); *see also id.* 119:14-25, 125:2-126:6.)

⁹⁶ (See e.g., Dep. of Judith Wolf 110:16-111:9, 376:15-377:2, Jan. 7, 2019 (Ex. 11 to Davidson Decl.); Dep. of Judith Wolf 410:6-17, 412:23-416:3, Sept. 13, 2021 (Ex. 12 to Davidson Decl.); Dep. of Judith Wolf 588:12-589:2, Sept. 14, 2021 (Ex. 13 to Davidson Decl.); Dep. of Judith Wolf 53:11-15, Apr. 25, 2024 (Ex. 14 to Davidson Decl.) ("[Q.] For purposes of your opinion in this case, are you quantifying any [e]ffect that asbestos has separate from talcum powder, the product itself? A. No. I mean, it's the entire product and asbestos is in that product."));

(cont'd)

Moreover, Dr. Saed, whose studies are the cornerstone of plaintiffs' experts' biological plausibility opinions, expressly disclaimed any reliance on asbestos and heavy metals in connection with his conclusion that talc causes ovarian cancer:

Q. Are your opinions in this case premised on talc containing asbestos?

A. (Witness shakes head from side to side.) I don't know, no, my opinion has nothing to do with that.

Q. Are your opinions in any way based on talc having heavy metals in them?

A. No.⁹⁷

Finally, courts around the country have rejected plaintiffs' experts' attempts to analyze the individual components of a substance, rather than the whole, in determining whether the substance caused a particular injury. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075 (S.D. Fla. Dec. 6, 2022)

Dep. of Shawn Levy 118:9-18, 121:16-122:11, 127:5-128:6, May 8, 2024 (Ex. 15 to Davidson Decl.) (testifying that his "opinions are -- were focusing on the totality of the product" and references to constituents were for "background"); Dep. of Jack Siemiatycki 55:20-56:7, Mar. 27, 2024 (Ex. 16 to Davidson Decl.); Dep. of Judith Zelikoff 270:1-272:4, 277:24-278:16, Jan. 21, 2019 (Ex. 17 to Davidson Decl.); Dep. of Rebecca Smith-Bindman 136:15-137:19, Feb. 7, 2019 (Ex. 18 to Davidson Decl.); Dep. of Laura Plunkett 272:24-273:6, Dec. 19, 2018 (Ex. 19 to Davidson Decl.) ("But on the issue of ovarian cancer, I'm looking at the data that has been collected on talc itself, which would be talc with the constituents that could include the metals"); Dep. of Laura Plunkett 182:23-25, Dec. 21, 2023 (Ex. 20 to Davidson Decl.) ("So the epidemiological literature related to perineal use of talc, it's talc with all the things in it."); Dep. of Sarah Kane 133:23-135:2, Jan. 25, 2019 (Ex. 21 to Davidson Decl.) ("what I am opining about is the ultimate product," not the constituents), 138:11-140:25, 288:16-23; 8/26/21 Clarke-Pearson Dep. 336:9-24.)

⁹⁷ (Dep. of Ghassan Saed 264:2-8, Jan. 23, 2019 (Ex. 22 to Davidson Decl.).)

(holding that it was correct to “fram[e] the general causation question *on the product the Plaintiffs consumed*, ranitidine, in lieu of the mechanistic theory by which the Plaintiffs seek to prove their case, [the ingredient] NDMA”) (emphasis added); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009); *Burst v. Shell Oil Co.*, No. CIV.A. 14-109, 2015 WL 3755953, at *9 (E.D. La. June 16, 2015), *aff’d*, 650 F. App’x 170 (5th Cir. 2016). For example, in *Henricksen* (one of plaintiffs’ own cited authorities), the plaintiff claimed that he became ill from exposure to the defendant’s gasoline because benzene is a component of the gasoline. The court rejected the plaintiff’s contention that his experts could simply rely on studies showing that benzene causes illnesses. According to the court, “[t]his is a products liability action and Defendant’s product is gasoline. It is undisputed that Henricksen’s exposure was to the mixture gasoline not simply the substance benzene. . . . The court cannot simply presume that the qualitative toxic and carcinogenic effects of benzene from *any source* are the same.” *Henricksen*, 605 F. Supp. 2d at 1156. Similarly, the *Burst* court rejected an expert’s attempt to analyze benzene separately from gasoline because “[t]he question here . . . is whether exposure to gasoline containing benzene can cause AML, not whether exposure to benzene generally can cause AML.” *Burst*, 2015 WL 3755953, at *9.

In short, plaintiffs apparently are taking the position that defendants' experts should not have analyzed cosmetic talc as a whole, even though this litigation is about cosmetic talc, all of the epidemiology they rely on involves cosmetic talc and their own experts largely (if not exclusively) focused their opinions on cosmetic talc. This argument is both procedurally improper and substantively frivolous. Accordingly, it should be rejected.

B. Drs. Saenz, Holcomb And Finan Properly Reject Plaintiffs' Experts' Biological Plausibility Opinions As Unsupported By Reliable Scientific Evidence.

Plaintiffs also argue that defendants' experts' opinions regarding biological plausibility are unreliable because they are "based on an incorrect standard requiring perfected 'proof' of migration, inflammation, and malignant transformation, rather than a plausible mechanism."⁹⁸ Plaintiffs further argue that: (1) Judge Wolfson previously ruled that proof of a biologically plausible mechanism is not required; (2) admitted Dr. Saenz's biological plausibility opinions in 2020 because they were not based on an assertion that "proof" of a mechanism was required; but (3) that prior ruling is inapplicable because Dr. Saenz and the other experts at issue have changed tack and "revert[ed] back to the incorrect 'proof' standard" in their current reports.⁹⁹

⁹⁸ (Pls.' Br. at 16.)

⁹⁹ (*Id.* (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 174-75).)

Plaintiffs' argument distorts defendants' experts' opinions, which are no different from those offered by Dr. Saenz and deemed admissible by Judge Wolfson. Drs. Saenz, Holcomb and Finan opine that Hill's biological plausibility factor is not satisfied because plaintiffs' proposed biological mechanisms are all hypotheses, not that plaintiffs' experts have failed to definitively prove or establish them. The biological plausibility factor requires more than an "untested mechanism hypothesis," even one that might be "possibly true." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d 213, 303, 305 (S.D.N.Y. 2018) (excluding mechanism opinion because it was "beset by analytic and evidentiary gaps at multiple steps"); *see, e.g., In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1295-96 (M.D. Fla. 2007) (excluding "unproven hypothesis"; "[W]hile [expert's] biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation."); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 534, 561-62 (W.D. Pa. 2003) ("While *Daubert* does not require absolute precision in identifying the medical mechanism of injury, there still must be 'sufficiently compelling proof that the agent must have caused the damages somehow.'") (citation omitted). Thus, while absolute certainty is not required, something more than guesswork is needed.¹⁰⁰

¹⁰⁰ Plaintiffs' authority does not support a contrary conclusion. *In re Fosamax Products Liability Litigation* involved a biological mechanism that was shown to (cont'd)

Plaintiffs’ attacks on defendants’ experts attempt to obscure the fact that all their experts can offer is guesswork.¹⁰¹ For example, plaintiffs fault Dr. Saenz for opining that “there must be ‘scientific proof’ of mechanism—i.e., ‘some proof that a particulate matter applied to the perineum can actually make it to the ovaries for the hypothesis that talc can cause ovarian cancer to be so.’”¹⁰² Although Dr. Saenz used the word “proof” in 2019 when testifying about biological plausibility, she

take place in rats and dogs and was so widely accepted that “[n]early every report and review of [the condition] point[ed] to” the proposed mechanism “as a likely mechanism.” 645 F. Supp. 2d 164, 182 (S.D.N.Y. 2009) (citation omitted) (cited in Pls.’ Br. at 19 n.37). No comparable evidence exists here. *In re Pfizer Inc. Securities Litigation* likewise involved a theory that had “been deemed plausible and credible in the relevant medical literature.” No. 04-9866, 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010), as amended (Mar. 29, 2010) (cited in Pls.’ Br. at 19 n.37). And *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011) (cited in Pls.’ Br. at 11), was described by the chair of the subcommittee that drafted the recent Rule 702 amendments as a “prime example of the problem” that the amendments were intended to solve, Thomas D. Schroeder, *Toward a More Transparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039, 2043-44 (2020).

¹⁰¹ Plaintiffs cite several cases for the proposition that the biological plausibility standard does not require scientific certainty. (See, e.g., Pls.’ Br. at 20 n.37 (citing *In re Trasylol Prods. Liab. Litig.*, No. 08-01928, 2010 WL 1489730, at *7-8 (S.D. Fla. Mar. 19, 2010), and *In re Hanford Nuclear Reservation Litig.*, No. 91-3015, 1998 WL 775340, at *7 (E.D. Wash. Aug. 21, 1998)).) But defendants never suggested that certainty is required to establish the biological plausibility factor. Rather, as explained above, defendants’ position is that biological plausibility requires something more than a hypothesis unsupported by any reliable science. *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 450 (S.D.N.Y. 2016) (“plausible hypothetical mechanism” does not support an inference of causation; “it may be a very good hypothesis begging for testing and further study, but it is only an untested hypothesis”) (citation omitted).

¹⁰² (Pls.’ Br. at 16 (citation omitted).)

was clearly not using that term in any legal sense; rather, it is clear from her testimony that when she said “there has to be some *proof*,” she simply meant there has to be some *evidence*. Indeed, Dr. Saenz explained at her deposition in 2019:

My understanding is that there has to be biologic evidence that what you’re hypothesizing could actually happen. It doesn’t have to be that you have to prove that talc itself could migrate, but there’s no studies of any migration whatsoever in the human that any particulate matter applied to the perineum can make it all the way to the ovaries.¹⁰³

In 2020, Judge Wolfson held that these opinions were admissible.¹⁰⁴ At her most recent deposition, Dr. Saenz offered similar testimony, explaining that plausibility means “it’s likely. There is a reasonable explanation for how that would occur.”¹⁰⁵ This testimony fully comports with Dr. Saenz’s report, which makes clear that “[i]n order to have biologic plausibility, there has to be *some* data to support the hypothesis.”¹⁰⁶

Plaintiffs also object to Dr. Holcomb’s testimony that he is “not convinced” that talc can cause ovarian cancer through migration or chronic inflammation

¹⁰³ (3/13/19 Saenz Dep. 198:11-18 (emphasis added).)

¹⁰⁴ *In re Johnson & Johnson*, 509 F. Supp. 3d at 196-97.

¹⁰⁵ (6/20/24 Saenz Dep. 338:11-15.)

¹⁰⁶ (Saenz 2024 MDL Rep. at 54; *see also* Rep. of Cheryl Saenz (“Saenz 2019 MDL Rep.”) at 30, Feb. 25, 2019 (Pls.’ Br. Ex. 23) (“A scientist cannot just say that because a hypothesis makes theoretical sense, it is so. Instead, scientific data are needed to support the contention, and . . . no data” support the theory being proffered.).)

because he has not seen any studies showing that chronic inflammation from talc, if it exists, is genotoxic.¹⁰⁷ But a closer reading of that testimony similarly demonstrates that Dr. Holcomb (like Dr. Saenz) was describing biological plausibility in terms of the lack of supportive evidence rather than definitive proof. For example, Dr. Holcomb testified: “I don’t think that there is good evidence that talc is able to get from someone’s perineum to their ovaries.”¹⁰⁸ Indeed, plaintiffs’ counsel directly asked Dr. Holcomb to provide his definition of “plausibility,” and Dr. Holcomb replied: “It’s just you have to have an explanation that at least is possible.”¹⁰⁹

Finally, plaintiffs complain that Dr. Finan “[b]ased his conclusions on the absence of precise studies.”¹¹⁰ But once again, the fact that Dr. Finan has opined that “there are no studies” demonstrating migration or malignant transformation¹¹¹ does not indicate that he applied the wrong standard for biological plausibility. As the Court has explained, “the relevant question is ‘whether the hypothesized causal link is credible in light of what is known from science and medicine about the

¹⁰⁷ (Pls.’ Br. at 17-18.)

¹⁰⁸ (6/7/24 Holcomb Dep. 108:20-109:23; *see also* Holcomb Rep. at 4 (“[P]laintiffs’ experts’ hypotheses regarding biologic plausibility ignore a host of contradictory studies.”).)

¹⁰⁹ (6/7/24 Holcomb Dep. 104:12-22.)

¹¹⁰ (Pls.’ Br. at 18.)

¹¹¹ (6/26/24 Finan Dep. 68:8-13.)

human body and the potentially offending agent.”” *In re Johnson & Johnson*, 509 F. Supp. 3d at 174 (citation omitted). Dr. Finan’s opinion that there is no “science” that supports plaintiffs’ experts’ biological plausibility opinions goes directly to that question—i.e., whether plaintiffs’ experts’ theory of biological plausibility is “credible.” *Id.*

In short, the testimony cited by plaintiffs does not suggest that Drs. Saenz, Holcomb and Finan imposed a “heightened standard” or an “incorrect . . . standard” for biological plausibility, much less that they “insist[ed] on certainty or near certainty.”¹¹² Rather, they merely explained that the opinions of plaintiffs’ experts are nothing more than bare “hypothes[es]” that are not supported by scientific data demonstrating that particulate matter applied to the perineum can travel to the ovaries and fallopian tubes.¹¹³ For these reasons, the Court should

¹¹² (Pls.’ Br. at 21-22.) Nor are defendants’ oncologists’ opinions inconsistent with the Court’s prior order. While the Court held that “biological plausibility is not the same as biological certainty,” *In re Johnson & Johnson*, 509 F. Supp. 3d at 174-75 (citation omitted), the Court did not find that defendants’ experts’ opinions were unreliable because they explained the lack of data supporting plaintiffs’ experts’ opinion. *See id.*

¹¹³ Plaintiffs also make the preposterous claim that the three experts conceded that there is a biologically plausible mechanism by which perineally applied talc can migrate to the fallopian tubes and ovaries (*see* Pls.’ Br. at 20-21), despite their repeated and unequivocal assertions to the contrary (*see, e.g.*, Saenz 2019 MDL Rep. at 22, 27-31; 3/13/19 Saenz Dep. 198:11-18, 233:21-25; Rep. of Kevin Holcomb at 3, 22, Feb. 25, 2019 (Ex. 23 to Davidson Decl.); 3/27/19 Holcomb Dep. 422:7-17). Again, this argument is directly refuted by the record. While Dr. Saenz testified that “there is some data that there can be particulate matter that can

(cont’d)

reject plaintiffs' argument that defendants' oncologists applied the wrong standard regarding biological plausibility.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court deny plaintiffs' motion to exclude the opinions of Drs. Finan, Saenz and Holcomb.

Dated: August 22, 2024

Respectfully submitted,

/s/ Susan M. Sharko

Susan M. Sharko

**FAEGRE DRINKER BIDDLE &
REATH LLP**

Allison M. Brown

Jessica Davidson

**SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP**

*Attorneys for Defendants Johnson &
Johnson and LLT Management, LLC*

make it to the ovaries" (3/13/19 Saenz Dep. 209:10-12 (quoted in Pls.' Br. at 20)), it is clear from context that she was referring only to a particular 1961 study by Egli & Newton, which did **not** involve talc (*id.* 209:9-210:7) and employed specific "conditions that were optimal for rapid transport" of the inserted particles, Egli & Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract*, 12(2) Fertil. Steril. 151, 152 (1961) (Ex. 24 to Davidson Decl.). Similarly, while Dr. Holcomb testified that it is "possible" that talc could migrate from the perineum to the ovaries (3/27/19 Holcomb Dep. 421:23-422:15 (quoted in Pls.' Br. at 20-21)), he clearly did not view that mere possibility as plausible (*id.* 422:11-17). Indeed, Dr. Holcomb testified that he is not aware of a single study showing that talc applied perineally migrated to a woman's ovaries or fallopian tubes. (*Id.* 438:24-439:4.)